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09/710,633	11/08/2000	Stephen B.H. Kent	TSRI 478.0C1	6210

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EXAMINER	
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ART UNIT	PAPER NUMBER
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/710,633
Filing Date: November 08, 2000
Appellant(s): KENT ET AL.

Donald G. Lewis
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 2, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

5.05

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 11-14 and 32 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 11-14 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure of derivatives of naturally isolatable proteins containing one or more variant or cysteine residues that are not found in the naturally isolatable protein (see claims 11 and 32). The original disclosure does not include the concept of altering a naturally-occurring protein's amino acid sequence by replacing amino acids with variant residues or cysteine residues or by inserting cysteine residues into the amino acid sequence so that a derivative of the naturally-occurring protein can be synthesized by the disclosed method.

(11) Response to Argument

With respect to the first, second, and fifth issues identified in the Brief, Appellants point to Example 4, pages 37-38, and to Scheme 9, page 39 (which was deleted from the specification and re-submitted as Figure 9 by the amendments filed on July 1, 2002 and March 17, 2003), as support for a disclosure of a derivative of a naturally isolatable protein containing one or more variant or cysteine residues that are not found in the naturally isolatable protein. However, this single species of the example does not provide support for the genus of protein derivatives recited in claims 11-14 and 32. In the example, a single lysine residue is replaced with a cysteine residue in an HIV protease. Claim 11 is significantly broader in scope, permitting the replacement of any number of the residues in any naturally isolatable protein with any variant

residue not limited to cysteine. The HIV protease of the example in the specification is not even a species of the mammalian proteins which are recited in claims 12-14. While claim 32 is limited to variant residues which are cysteine residues, it recites that an unlimited number of variant cysteine residues can be present. The single species disclosed in Example 4 does not constitute a representative number of species sufficient to support the newly claimed genera of claims 11 and 32, which literally embrace an infinite number of protein derivatives. The original disclosure does not set forth any species which fall within the metes and bounds of claims 12-14. Zero species is not a representative number of species which can support the newly claimed genera of claims 12-14.

Further, claims 11-14 permit the replacement of any number of naturally-occurring residues with any variant amino acid including non-cysteine residues. Claims 11-14 embrace variations at positions where native chemical ligation is not going to occur, and embrace variant residues which would not permit native chemical ligation to occur. Claim 32 also embraces variations at positions where native chemical ligation is not going to occur. Again, the specific disclosure of the specification does not provide written descriptive support for the new claim limitations.

At page 11 of the Brief, Appellants contend that the HIV-1 protease of Example 4/Figure 9 is a human viral protein which is synthesized in vivo using human protein biosynthetic pathways. It appears that Appellants are arguing that the HIV-1 protease of Example 4/Figure 9 is therefore a mammalian and a human protein and encompassed by instant claims 12 and 13. (Appellants apparently do not contend that HIV-1 protease is a human cytokine as is recited in claim 14.) However, this argument contradicts the ordinary meaning given to the terms

"mammalian protein" and "human protein". If the protein is not encoded by the mammalian or human genome, it is not a mammalian or human protein. Regardless of the physical location where the virus might replicate, a protein which is only encoded by a lethal virus is not a mammalian protein or a human protein by any reasonable definition of the terms.

Appellants also point to more generic disclosure at page 7, bottom of first paragraph, and at page 21, second paragraph, as supporting the new claim language. However, these sections of the specification do not discuss the replacement of naturally occurring amino acids with variant residues. The recitation of "variation of the covalent structure of the protein molecule" or "variation of protein covalent structure" does not constitute the "full, clear, concise, and exact disclosure" of unlimited amino acid substitution required by 35 U.S.C. 112, first paragraph. To the extent that one skilled in the art might infer that these sections of the specification are concerned with replacement of amino acid residues with cysteine residues due to their references to native chemical ligation, this would not provide support for the new claim language in claims 11-14, which permits the variant residues to be amino acids other than cysteine and which permit the variant residues at locations other than where native chemical ligation is to occur.

With respect to the third issue identified in the Brief, it is acknowledged that literal support in the original disclosure is not a requirement for adequate written description of new claim language under 35 U.S.C. 112, first paragraph. That is why it is necessary to consider all the disclosure, e.g., the species of Example 4 and Figure 9, in order to determine whether new claim language satisfies 35 U.S.C. 112, first paragraph. However, Example 4 and Figure 9 fail to provide support for the new claim language because there is no disclosure of the significance of the cysteine residue which is present at position 41 of the HIV protease. Clearly, in view of

Appellants' disclosure, a cysteine residue is required to be present at the N-terminus of one of the oligopeptides being ligated in order for the reaction to proceed. However, Example 4 and Figure 9 never discuss why a cysteine residue is present at position 41. The cysteine's occurrence is presented as a fact without any analysis of its significance. Without any discussion of the significance of the cysteine residue at position 41, one skilled in the art would not extrapolate from the single example to the concept that substitution of cysteine residues for naturally-occurring residues is a general reaction technique which can be used for the synthesis of proteins in general.

With respect to the fourth issue identified in the Brief, the examiner accepts Appellants' interpretation of their statement in the specification, and does not rely upon the statement to support the rejection. It is noted that this section of the specification was not cited in any statement of the rejection, and was only referred to in the remarks accompanying the final rejection.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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JRussel
August 9, 2005

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